December 19, 2018

BrainScope Company Inc.
Michael Singer
CEO
4350 East West Hwy, Ste 1050
Bethesda, Maryland 20814

Re: K181785
Trade/Device Name: Modified BrainScope One
Regulation Number: 21 CFR 882.1450
Regulation Name: Brain injury adjunctive interpretive electroencephalograph assessment aid
Regulatory Class: Class II
Product Code: PIW, PKQ, OLU
Dated: November 28, 2018
Received: November 28, 2018

Dear Michael Singer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181785

Device Name
BrainScope One

Indications for Use *(Describe)*

• BrainScope One is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury within the past 72 hours (3 days), are between the ages of 18-85 years, have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion / mild traumatic brain injury (mTBI)), and are being considered for a head CT. BrainScope One should not be used as a substitute for a CT scan.
• The BrainScope One Structural Injury Classification ("SIC") uses brain electrical activity to determine the likelihood of structural brain injury visible on head CT. Negative likely corresponds to those with no structural brain injury visible on head CT. Positive likely corresponds to those with a structural brain injury visible on head CT. Equivocal may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.
• BrainScope One provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment.
• The BrainScope One device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (QEEG) parameters from frontal locations on a patient's forehead. The BrainScope One calculates and displays raw measures for the following standard QEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. These raw measures are intended to be used for post hoc analysis of EEG signals for interpretation by a qualified user.
• BrainScope One also provides clinicians with quantitative measures of cognitive performance to aid in the assessment of an individual's level of cognitive function. These measures do not interact with any other device measures, and are stand alone.
• BrainScope One also stores and displays electronic versions of standardized clinical assessment tools that should be used in accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY[1]

Submitter:	BrainScope® Company, Inc. 4350 East West Highway Suite #1050 Bethesda, MD 20814 Phone: (240) 752-7680 Fax: (240) 752-7679 www.brainscope.com
Contact:	Michael E. Singer, Ph.D. Chief Executive Officer BrainScope Company, Inc. Phone: (240) 752-7677 Fax: (240) 752-7679 Email: michael.singer@brainscope.com
Prepared By:	Sabyasachi Roy, Ph.D. Director Regulatory Affairs, Quality Assurance & Compliance
Device Proprietary Name:	Modified BrainScope One
Device Common Name:	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid
Device Classification Name:	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid
Classification Regulation:	21 CFR § 882.1450
Panel:	Neurology
Product Codes:	PIW, PKQ, OLU
Predicate Device:	BrainScope One (K181179)

[1] Prepared in accordance with 21 CFR § 807.87(h) and 21 CFR § 807.92(c).

Device Description:
The Modified BrainScope One is a portable, non-invasive, non-radiation emitting, point of care device intended to provide results and measures to support clinical assessments to aid in the diagnosis of concussion / mild traumatic brain injury (mTBI). It also contains configurable, selectable cognitive performance tests and digitized standard assessment forms. The combination of multi-modal, multi-parameter capabilities is intended to provide a panel of measures to further support the clinical assessment of head injury. BrainScope One provides healthcare professionals with a set of well-developed and researched concussion assessment tools.

Indications for Use:[2]

The modified BrainScope One's Indications for Use are as follows:

- BrainScope One is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury within the past 72 hours (3 days), are between the ages of 18-85 years, have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion / mild traumatic brain injury (mTBI)), and are being considered for a head CT. BrainScope One should not be used as a substitute for a CT scan.
- The BrainScope One Structural Injury Classification ("SIC") uses brain electrical activity to determine the likelihood of structural brain injury visible on head CT. Negative likely corresponds to those with no structural brain injury visible on head CT. Positive likely corresponds to those with a structural brain injury visible on head CT. Equivocal may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.
- BrainScope One provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment.
- The BrainScope One device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (QEEG) parameters from frontal locations on a patient's forehead. The BrainScope One calculates and displays raw measures for the following standard QEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. These raw measures are intended to be used for post hoc analysis of

[2] The differences between the modified BrainScope One and its predicate (BrainScope One) do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. The subject and predicate devices have the same overall intended use.

EEG signals for interpretation by a qualified user.

- BrainScope One also provides clinicians with quantitative measures of cognitive performance to aid in the assessment of an individual's level of cognitive function. These measures do not interact with any other device measures, and are stand alone.
- BrainScope One also stores and displays electronic versions of standardized clinical assessment tools that should be used in accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.

Table 1: Indications for Use Comparison to Predicate device

Proposed Device: Modified BrainScope One	Predicate: BrainScope One	Comments
BrainScope One is a multi-modal, multi-parameter assessment indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury within the past 72 hours (3 days), are between the ages of 18-85 years, have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion / mild traumatic brain injury (mTBI)), and are being considered for a head CT. BrainScope One should not be used as a substitute for a CT scan.	BrainScope One is indicated for use as an adjunct to standard clinical practice to aid in the evaluation of patients who are being considered for a head CT, who sustained a closed head injury within 72 hours, present with a Glasgow Coma Scale score (GCS) of 13-15 (including concussion / mild Traumatic Brain Injury (mTBI)), and are between the ages of 18-85 years. BrainScope One should not be used as a substitute for a CT scan.	Expanded to include multi-modal and multi-parameter assessment.
The BrainScope One Structural Injury Classification ("SIC") uses brain electrical activity to determine the likelihood of structural brain injury visible on head CT. Negative likely corresponds to those with no structural brain injury visible on head CT. Positive likely corresponds to those with a structural brain injury visible on head CT. Equivocal may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.	A negative BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with no structural brain injury visible on head CT. A positive BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, likely corresponds to those with a structural brain injury visible on head CT. An equivocal BrainScope One Structural Injury Classification using brain electrical activity in patients who sustained a closed head injury within 72 hours, may correspond to structural brain injury visible on head CT or may indicate the need for further observation or evaluation.	Equivalent. Combined for clarity.
BrainScope One provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG), aiding in the evaluation of head injury as part of a multi-modal, multi-parameter assessment.	The BrainScope One provides a measure of brain function (EEG Brain Function Index, (BFI)) for the statistical evaluation of the human electroencephalogram (EEG).	Equivalent. Clarification of device capabilities.

Proposed Device: Modified BrainScope One	Predicate: BrainScope One	Comments
The BrainScope One device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (QEEG) parameters from frontal locations on a patient's forehead. BrainScope One calculates and displays raw measures for the following standard QEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. These raw measures are intended to be used for post hoc analysis of EEG signals for interpretation by a qualified user.	The BrainScope One device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (QEEG) parameters from frontal locations on a patient's forehead. BrainScope One calculates and displays raw measures for the following standard QEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. These raw measures are intended to be used for post hoc analysis of EEG signals for interpretation by a qualified user.	Same
BrainScope One also provides clinicians with quantitative measures of cognitive performance to aid in the assessment of an individual's level of cognitive function. These measures do not interact with any other device measures, and are stand alone.	BrainScope One also provides clinicians with quantitative measures of cognitive performance to aid in the assessment of an individual's level of cognitive function. These measures do not interact with any other device measures, and are stand alone.	Same
BrainScope One also stores and displays electronic versions of standardized clinical assessment tools that should be used in accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.	BrainScope One also stores and displays electronic versions of standardized clinical assessment tools that should be used in accordance with the assessment tools' general instructions. These tools do not interact with any other device measures, and are stand alone.	Same

Comparison of Technological Characteristics with the Predicate Device:

The Modified BrainScope One incorporates additional clarification in the Indications for Use statement of its predicate (BrainScope One) to accommodate widely accepted definitions for "concussion" and "mild Traumatic Brain Injury (mTBI)". The core capabilities of the Modified BrainScope One and its fundamental scientific technology remain unaltered compared to the BrainScope One (predicate). The device modifications discussed do not alter the BrainScope One's safety or effectiveness and neither do they change its intended use compared to the predicate. The Modified BrainScope One is substantially equivalent to the predicate BrainScope One.

Table 2, Technological Comparison to Predicate Device

Topic / Area	Proposed Device: Modified BrainScope One	Predicate: BrainScope One	Comments
Platform	Trimble T41 mobile device, Android OS	Trimble T41 mobile device, Android OS	Same
Processed EEG Bandwidth	1kHz sampled data with DC to 300Hz bandwidth and 100Hz sampled data with 0.67Hz to 43Hz bandwidth	1kHz sampled data with DC to 300Hz bandwidth and 100Hz sampled data with 0.67Hz to 43Hz bandwidth	Same
Common Mode Rejection Ratio (CMRR)	< -100 dB (or better)	< -100 dB (or better)	Same
System Noise Floor	< 0.4 µV in 0.67 Hz to 43Hz bandwidth	< 0.4 µV in 0.3 Hz to 43Hz bandwidth	Same
ADC Resolution	45 nV/bit	45 nV/bit	Same
ADC Sampling Rate	1000 Hz, down sampled to 100 Hz for algorithm processing	1000 Hz, down sampled to 100 Hz for algorithm processing	Same
Electrode Placement System	The International 10-20 System	The International 10-20 System	Same
Electrode Positions Utilized	Fp1, Fp2, Fpz, AFz, F7, F8, A1, A2	Fp1, Fp2, Fpz, AFz, F7, F8, A1, A2	Same
Electrode Material	Single use Ag/AgCl electrode sensor array headset with solid gel	Single use Ag/AgCl electrode sensor array headset with solid gel	Same
Real Time EEG Display	Yes	Yes	Same
Classification	Three tier classification	Three tier classification	Same

Topic / Area	Proposed Device: Modified BrainScope One	Predicate: BrainScope One	Comments
Algorithm (Structural Injury Classification)	with results of Negative, Equivocal and Positive outputs.	with results of Negative, Equivocal and Positive outputs.	
Results Presentation and Reporting Features	Specific raw measures. EEG playback. Structural injury classification and brain function index display. Cognitive performance raw and standard scores including percentiles. Electronic versions of Standard Clinical Assessments.	Specific raw measures. EEG playback. Structural injury classification and brain function index display. Cognitive performance raw and standard scores including percentiles. Electronic versions of Standard Clinical Assessments.	Equivalent. Same primary functionality with minor enhancements made to user interface in modified BrainScope One.

Performance Data:

The Pre-Specified analyses for the BFI (described in SAR for submission K161068) included a multinomial logistic regression analysis comparing the odds ratio of groups with differing levels of functional impairment, as determined by assessments from conventional concussion symptom scales, to a control group, as well as ANOVAs between these groups. Post-hoc analyses were performed to explore the relationship between conventional concussion symptom scales and the BFI, as well as the relationship between differing levels of functional impairment and the BFI.

All clinical performance data from the Ahead 300 (K161068) submission still apply.

The Modified BrainScope One device, like its predicate (BrainScope One), is compliant to the following standards:

- IEC 60601-1/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2/A1;2007 Medical electrical equipment - Section1.2 Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6/A1:2013 General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- IEC 60601-2-26:2012 Particular requirements for the basic safety and essential performance of electroencephalographs
- ANSI/AAMI EC12:2000/(R)2010 Disposable ECG Electrodes

- ANSI/AAMI/ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ANSI/AAMI/ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ANSI/AAMI/ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization
- MIL-STD-810G, Department of Defense Test Method Standard for Environmental Engineering Considerations and Laboratory Tests
- IEC 60529 (2004) Degree of Protection Provided by Enclosures
- ASTM D4169 – 09, Standard Practice for Performance Testing of Shipping Containers and Systems

Conclusion:

The Modified BrainScope One has the same intended use and same technological characteristics as the predicate device (BrainScope One). The minor differences between the Modified BrainScope One and the predicate (BrainScope One) do not raise new questions of safety and effectiveness. Performance data establish that the modified BrainScope One is as safe and effective as the predicate (BrainScope One).

The Modified BrainScope One is substantially equivalent to the predicate (BrainScope One).